



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 4, 2015

NxStage Medical, Inc.
Mary Lou Stroumbos
Director, Regulatory Affairs
350 Merrimack Street
Lawrence, MA 01843

Re: K150472
Trade/Device Name: NxStage System One
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: ODN
Dated: May 4, 2015
Received: May 5, 2015

Dear Mary Lou Stroumbos,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150472

Device Name

NxStage System One

Indications for Use (Describe)

The NxStage System One is indicated for the treatment of acute and chronic renal failure, or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician's prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification**

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

A. Date Prepared: February 20, 2015

B. Submitter's Information:

Name: NxStage Medical, Inc.

Address: 350 Merrimack Street
Lawrence, MA 01843

**FDA Establishment
Owner/Operator
Number:** 9045797

Contact Person: Mary Lou Stroumbos
Director, Regulatory Affairs

Phone: (978) 687-4872

Fax: (978) 687-4750

Manufacturer: NxStage Medical, Inc.
350 Merrimack Street
Lawrence, MA 01843

**FDA Establishment
Registration Number:** 3003464075

Sterilization Site: Steris Isomedix (NxStage Cartridge
Express)
1000 S. Sarah Place
Ontario, CA 91761

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

C. Device Name:

Trade/Proprietary Name:	NxStage System One
Common/Usual Name:	Hemodialysis System
Classification Name:	High Permeability Hemodialysis System
Regulation Number:	876.5860
Product Code:	ODN
Device Classification:	Class II
Device Panel:	Gastroenterology/Urology

D. Substantial Equivalence:

The NxStage System One has the same intended use and utilizes the same fundamental technology as the predicate NxStage System One. The NxStage System One has been compared to the legally marketed predicate device as cleared through K141752 (December 19, 2014) and was found to be substantially equivalent.

E. Device Description/Indications for Use:

The NxStage System One is comprised of the NxStage Cyclor, an electromechanical control unit; the NxStage Cartridge, a sterile, single-use extracorporeal blood and fluid management circuit (with or without a pre-attached high permeability filter) that mounts integrally within the NxStage Cyclor. The combined system is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility. The NxStage System One is also indicated for home hemodialysis, including home nocturnal hemodialysis.

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

Indications for use:

The NxStage System One is indicated for the treatment of acute and chronic renal failure or fluid overload using hemofiltration, hemodialysis, and/or ultrafiltration, in an acute or chronic care facility.

The System is also indicated for home hemodialysis, including home nocturnal hemodialysis.

All treatments must be administered under physician’s prescription, and must be performed by a trained and qualified person, considered to be competent in the use of this device by the prescribing physician.

F. Technological Characteristics:

The proposed device has the same technological characteristics and is identical in design and configuration as compared to the predicate device. The proposed device is designed with similar software, components and features also used in the predicate device.

Table 1 Device Technological Characteristics Comparison Table		
<i>Parameter</i>	Proposed Device NxStage System One	Predicate Device NxStage System One (K141752)
<i>Intended Use</i>		
<i>Hemodialysis</i>	Yes	Yes
<i>Hemofiltration</i>	Yes	Yes
<i>Ultrafiltration</i>	Yes	Yes
<i>Technology / Components:</i>		
<i>Pumps</i>	Same	4 peristaltic pumps
<i>Valves (clamps)</i>	Same Same	2 solenoid actuated pinch clamps 8 cam driven pinch clamps
<i>Air / fluid detectors</i>	Same	3 ultrasonic air/ fluid detectors
<i>Blood leak detector</i>	Same	1 optical blood leak detector
<i>Pressure transducers</i>	Same	5 electronic pressure transducers
<i>Temperature sensors</i>	Same	1 electronic temperature sensor

NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification

Table 1 Device Technological Characteristics Comparison Table										
Parameter	Proposed Device NxStage System One	Predicate Device NxStage System One (K141752)								
<i>Flow Rates:</i>										
<i>Blood</i>	Same	10-600 ml/min								
<i>Prescription Fluid /Dialysate Flow</i>	Same	0-18000 ml/hr								
<i>Ultrafiltration</i>	Same	0-2400 ml/hr								
<i>Transmembrane Pressure Monitoring Specification</i>	Same	Yes								
<i>Venous Pressure Monitor</i>	Same	0 to 400 mmHg								
<i>Effluent fluid Pressure Monitor</i>	Same	0 to 500 mmHg								
<i>Air Detector</i>	Same	Reduction of detector signal lasting 6 ms minimum (Approximates a 60 micro liter bubble at 400 mmHg venous pressure and 600 ml/min blood flow)								
<i>Blood Leak Detector</i>	Same	15% reduction in detector signal lasting 20 seconds minimum. Signal reduction % based on a 0.35 ml/min leak rate of 32 Hct blood.								
<i>Effluent Volume Accuracy</i>	Same	<p>Greater of 300 ml/ 12 hr or 3% of exchange volume (For software versions 4.7 and below)</p> <p>For software versions 4.8 and higher:</p> <table border="1"> <tr> <th>Therapy Fluid Flow Rate L/hr)</th><th colspan="2">Specification greater of</th></tr> <tr> <td>> 3</td><td rowspan="2">+ 5% UF* or</td><td>±100 ml/hr*</td></tr> <tr> <td>≤ 3</td><td>± 25 ml/hr*</td></tr> </table> <p>*Representing 95/90 tolerance interval established under controlled laboratory testing conditions.</p>	Therapy Fluid Flow Rate L/hr)	Specification greater of		> 3	+ 5% UF* or	±100 ml/hr*	≤ 3	± 25 ml/hr*
Therapy Fluid Flow Rate L/hr)	Specification greater of									
> 3	+ 5% UF* or	±100 ml/hr*								
≤ 3		± 25 ml/hr*								
<i>IV Prescription Fluid</i>	Same	Off-line, sterile- physician prescribed, indicated for infusion								
<i>Dialysate</i>	Same	Dialysate available as pre-packaged pre-mixed sterile fluids or via the PureFlow SL (K043436 K060296, K090919, K111174 & K140571)								
<i>Compatible Blood Tubing Set</i>	Same	NxStage Standard Cartridge								
<i>Software</i>	Same	Software version 4.10								

Special 510(k) Premarket Notification
NxStage Medical, Inc.

**NxStage Medical, Inc.
NxStage System One
510(k) Premarket Notification**

G. Summary of Non-Clinical Test/Performance Testing – Bench and Clinical Testing

NxStage believes that the information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indications for use. Performance, verification and validation testing was conducted to characterize performance of the proposed device and the predetermined acceptance criteria were met.

The following non-clinical testing was conducted:

- Simulated treatments

The following clinical testing was conducted:

No Clinical testing was conducted

Conclusion: Results of the non-clinical testing have documented that the proposed NxStage System One is substantially equivalent to the predicate device and is suitable for the labeled indications for use.